

K082112 (P3. 1 of 2)

AUG 27 2008

T2™ Spinal System
510(k) Summary
July 2008

I. Company: Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Melisa Lansky, M.B.A.
Sr. Regulatory Affairs Specialist

II. Product Name: T2™ Spinal System
Classification: MQP

III. Description: The T2™ Spinal System is a distractible system used in corpectomy procedures. This construct is inserted between two vertebral bodies in the thoracic and/or lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The construct is not intended to be used as a stand alone device. The construct is intended to be used with either anterior and/or posterior supplemental spinal fixation systems already cleared for thoracic and lumbar spine stabilization.

The T2 XVBR™ expanding cage is made of titanium alloy, cobalt chrome, and nitinol. The T2 XVBR™ end caps, baskets, and covers are attached to the T2 XVBR™ expanding cage to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

T2™ Spinal System constructs may not be used with stainless steel supplemental fixation devices. Titanium constructs comprised from one of the following Medtronic spinal systems or their successors must be used with the T2™ Spinal System.

	Anterior	Posterior
ZPLATE-II™ Anterior Fixation System	X	
DYNALOK CLASSIC® Spinal System	X	X
VANTAGE® Anterior Fixation System	X	
TSRH® Spinal System	X	X
CD HORIZON® Spinal System	X	X

IV. **Indications for Use:** The T2™ Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2™ components consist of a series of end caps, baskets, and covers which must be attached to a T2 XVBR™ expanding centerpiece to form a complete construct. The final construct is to be used with supplemental fixation. The T2 SCEPTOR™ components also serve as a vertebral body replacement device for the same intended use in the thoracolumbar spine. The T2 SCEPTOR™ end caps and endcleats must be attached to a PYRAMESH-C® device to form a complete construct. Both constructs (T2 XVBR™ and T2 SCEPTOR™) must be used with supplemental fixation to form a final construct. Specifically, the construct is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNALOK CLASSIC® Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2™ Spinal System construct is intended to be used with bone graft.

V. **Substantial Equivalence:** Documentation was provided which demonstrated that the T2™ Spinal System components are substantially equivalent to previously cleared vertebral body replacement devices, including itself.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2008

Medtronic Sofamor Danek
% Ms. Melisa Lansky,
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K082112

Trade Name: T2 Spinal System
Regulation Number(s): 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 23, 2008
Received: July 28, 2008

Dear Ms. Lansky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Melisa Lansky

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 2008

510(k) Number (if known): K08212

Device Name: T2™ Spinal System

Indications for Use:

The T2™ Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2™ components consist of a series of end caps, baskets, and covers which must be attached to a T2 XVBRTM expanding centerpiece to form a complete construct. The final construct is to be used with supplemental fixation. The T2 SCEPTORTM components also serve as a vertebral body replacement device for the same intended use in the thoracolumbar spine. The T2 SCEPTORTM end caps and endcleats must be attached to a PYRAMESH-C® device to form a complete construct. Both constructs (T2 XVBRTM and T2 SCEPTORTM) must be used with supplemental fixation to form a final construct. Specifically, the construct is to be used with the Medtronic ZPLATE IITM Anterior Fixation System, the DYNALOK CLASSIC® Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2™ Spinal System construct is intended to be used with bone graft.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K08212